

## Original Research Article

## **A study of Efficacy and Safety of Intravenous Iron sucrose for the treatment of Severe Anaemia in antenatal and postnatal women at community Health Center, Prantij, Gujarat, India**

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**Abstract:** Anaemia is a leading cause of maternal death in the world. In the world about 50% maternal deaths occur in south-east Asia and in south east asia, 80% maternal death occur in India due to anaemia. The traditional treatment of iron deficiency anaemia includes oral iron and blood transfusion. Both of these have their own drawback so now IV infusion of iron sucrose is first line for the therapy of moderate to severe anaemia. So this study is done with the objective to determine the iron sucrose efficacy and safety in treatment of iron deficiency anemia. This was a prospective study. Total 102 patient having Hemoglobin between 4-7 gm/dL were included in the study. Intravenous Iron sucrose was started as per national guideline. The study subjects were examined to record their haemoglobin level and asked about adverse effects after 3 dose (1 week) and 6 dose (2 week). Recorded data was entered in MS Excel 2016. Result published as percentage and mean. During the first two week almost 1.2 gm% increase in Hb level after every week (after 3 dose). Swelling at injection site was most common (8.8%) adverse effect observed in 1<sup>st</sup> dose as well as in subsequent doses. Delayed hypersensitivity was reported in 3 cases in subsequent doses. As per this result conclude that Intravenous infusion of iron sucrose is very effective in iron deficiency anaemia. It increases Hb level at a faster rate than other known iron preparation.

**Keywords:** Iron deficiency Anaemia, Iron sucrose

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**INTRODUCTION**

Anaemia is a condition in which the number of red blood cells or their oxygen-carrying capacity is insufficient to meet physiologic needs, which vary by age, sex, altitude, smoking, and pregnancy status. Among various type of anaemias Iron deficiency anaemia is the most common type of anaemia having almost 20-50 % prevalence in the world [1, 2]. Prevalence of anaemia in India is the highest in the world[3].

Anaemia is a very important risk factor for pregnancy. The causes for anaemia in pregnancy include increased iron demand during pregnancy, low iron contain in diet, repeated pregnancies and pre-existing anaemia[4]. WHO defines anaemia as haemoglobin level <11gm% and haematocrit<33% in pregnancy[5]. Anaemia is the most common reason for maternal death in the world[6]. About half of the global maternal deaths due to anaemia occur in South-east

Asian countries. Among south east Asia countries, 80% deaths occur in only one country, India[7]. In Gujarat state 60.8% pregnant women are anaemic and 3.8 % have severe anaemia[8].

Early detection and proper management of iron deficiency anaemia can lead to substantial reduction in pre term labour, pre-eclampsia, infection, haemorrhage, IUGR, low birth weight, undernutrition in childhood, adolescent and improvement in adult height[9].

Oral iron supplements to women for the prevention of iron deficiency anaemia is the most widely practiced public health measure in India. Even if this measure if anaemia occur, the traditional treatment includes oral iron, parenteral iron and blood transfusion[9]. Among these therapies, Oral iron is associated with side effects, takes a long time to correct anaemia and many times poor compliance by patients. Second option is parenteral iron preparation like iron dextran and iron sorbitol. They are associated

with anaphylactic reactions. Third and last option is blood transfusion. It is associated with cross reactions and viral infections and also not possible at PHCs and CHCs level where blood bank is not available[9].

On the other side an alternate therapeutic agent Intravenous iron sucrose has very less side effects and can be used for the rapid correction of anaemia or restoring iron stores[10].

As iron sucrose is started only few years ago in India, not many research about efficacy of it in pregnant and postnatal women with a large sample size, so this study was chosen with a view to check efficacy of iron sucrose in patients and any adverse effect.

## MATERIALS & METHODS

This prospective study was carried out at Community health center, Prantij, Gujarat. The study period was from August, 2015 to July 2016. All pregnant and postnatal women came to Obstetric clinic having haemoglobin level between 4 to 7 g/dL were taken as a study population. Total 438 patients attended the clinic during the study period. Exclusion criteria were patients not giving consent, haematological disease other than iron deficiency anaemia, known hypersensitivity to iron, history or need of blood transfusion and history of chronic medical disorders. Patients interrupt the therapy were also excluded. Thus 102 patients were left as study subject.

Before beginning the therapy oral iron is stopped as per national guideline and a Tab Albendazole (400 mg) was given to each patient. Haemoglobin level of the study subjects were carried out. Dose of IV iron sucrose was calculated by formula given below:

Total iron (in mg) = {2.4 X Body Weight in kg X Hb% deficient (11- actual Hb%)} + 500

Calculated dose was given by IV infusion in divided doses. Doses were given on alternate days up to 3 times a week. 200 mg iron sucrose was diluted in 100 ml of isotonic sodium chloride solution to be given over period of half hour during each dose. patients were monitored for 1 hour after first dose and half hour after every subsequent infusion for any adverse effect. Test dose was not given but anaphylactic kit was kept ready.

The study subjects were examined to record their haemoglobin level and asked about adverse effects after 3 dose (1 week) and 6 dose(2 week).

Collected data was entered in MS excel 2016 and analysis was also done in same software. The results are presented as percentage and mean.

## RESULTS

Among 102 participants who received 6 doses of iron sucrose, 47.1% were in age group of 20 to 25 years followed by 28.4% in age group of 26 to 30 years. Majority of pregnant women (80.4%) belong to general caste. 40.2% women were first gravida followed by 35.3% women who were in second gravida. [Table 1]

Table 2 shows comparative analysis of adverse effects in 1<sup>st</sup> dose and subsequent doses shows that Swelling at injection site was most common (8.8%) adverse effect observed in 1<sup>st</sup> dose as well as in subsequent doses. Delayed hypersensitivity was also reported in 3 cases in subsequent doses.

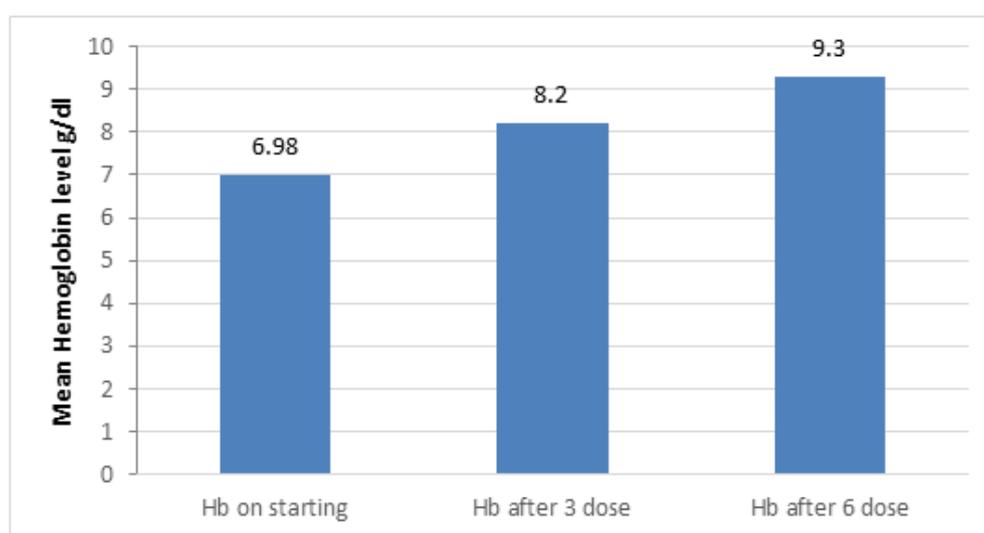
As shown in figure 1 Mean Hb of all pregnant women at the start of the treatment was 6.98 gm% which increased to 8.2 gm % after 3 doses of iron sucrose and 9.34 gm% after 6 doses of treatment. Thus almost 1.2 gm% increase in Hb level every week (3 dose).

**Table 1: Basic demographic distribution of pregnant women on iron sucrose therapy**

	Number of women	Percentage
<b>Age group</b>		
<20	14	13.7
20-25	48	47.1
26-30	29	28.4
>30	11	10.8
<b>Caste</b>		
Gen	82	80.4
SC	14	13.7
ST	06	5.9
<b>Gravidity</b>		
1	41	40.2
2	36	35.3
≥3	25	24.5
PNC	00	0.0
<b>Total</b>	<b>102</b>	

**Table 2: Comparative analysis of adverse effects on iron sucrose in 1<sup>st</sup> and subsequent doses**

Adverse Effect	After 1 <sup>st</sup> dose N (%)	After Subsequent doses N (%)
<b>GIT Effects</b> Nausea, Vomiting, Dyspepsia	0(0.0%)	0(0.0%)
<b>Constipation</b>	0(0.0%)	0(0.0%)
<b>Diarrhoea</b>	0(0.0%)	0(0.0%)
<b>Blurred vision</b>	0(0.0%)	01(1.0%)
<b>Vertigo</b>	03(2.9%)	02(2.0%)
<b>Muscle pain/joint pain</b>	04(3.9%)	02(2.0%)
<b>Swelling at injection site</b>	09(8.8%)	09(8.8%)
<b>Pruritus</b>	04(3.9%)	03(2.9%)
<b>Anaphylaxis</b>	0(0.0%)	0(0.0%)
<b>Delayed hypersensitivity</b>	0(0.0%)	03(2.9%)

**Fig-1: Comparison of mean Hb level after treatment with iron sucrose**

## DISCUSSION

Anaemia during pregnancy causes risk of haemorrhage and other related complications of IDA resulting in increased in mortality and morbidity in these women. Intravenous iron sucrose is safe in pregnancy, corrects anaemia in short duration and replenishes iron stores better than oral iron.

In a study conducted by Uma Gupta et al involving 36 pregnant women with moderate to severe anaemia, two doses of iron sucrose raised mean Hb level significantly after 14 and 28 days of treatment. In same study, minor side effects were noted in few cases (pain at injection site- one, metallic taste- three, headache- one, warm tingling sensation-two cases). Majority of the patients were free of side effects (80.56%)[5].

Studies comparing IV iron sucrose and oral iron therapy in pregnancy, have shown significant improvement in haematological parameters, early

replenishments of iron stores with no serious adverse effects[11,12,13,14].

IV iron sucrose is safe and more effective than intramuscular iron therapy in treatment of anaemia[15]. Dropout rates are higher in intramuscular groups and majority complained of pain in injection site. The blood transfusion rates are also reduced in patients treated with IV iron sucrose[15,16].

IV iron sucrose becomes therapeutic mainstay for severely iron-deficient mothers when they are unable to take oral preparations[17]. In practice, physician often face poor compliance, justified by digestive side effects leading to worsening of anaemia. In these cases, IV iron sucrose of administration is indicated[18].

Pregnancy as such is a risky situation for a woman to lose blood during delivery, and woman who are anaemic prenatally are at a higher risk of life and complications due to blood loss during delivery. Many

of our pregnant women who are anaemic do not tolerate oral iron or have adverse effects with other parenteral iron preparations. Blood transfusion for management of anaemia in pregnancy has many problems like availability; spread of infection, cost, blood transfusion reactions etc.[19], In this context, iron sucrose has a very important role because of its efficacy and safety. The cost of iron sucrose compared other modalities of treatment is affordable.

In our country more than 59.9% of pregnant women are anaemic. The major cause for maternal mortality and morbidity is due to anaemia directly or indirectly. Iron sucrose therapy in treatment of anaemia in pregnancy reduces maternal mortality and morbidity to a significant level.

Iron sucrose is definitely the first line of treatment of severe anaemia in pregnancy in view of its easy accessibility, safety and finally good efficacy compared to other parenteral iron and blood transfusion[20]. But the oral iron supplementation in pregnancy is time tested and tried drug, still to be continued for prevention of anaemia in pregnancy as incorporated in our National health programme.

#### CONCLUSION

Intravenous infusion of iron sucrose is very effective in iron deficiency anaemia. It increases Hb level at a faster rate than other known iron preparation. It is also very safe and Adverse effects are minimal. Side effects are also decreased with subsequent doses.

#### RECOMMENDATION

As Intravenous iron sucrose is rapid, safe and effective; it can be used as a good alternative to other parenteral iron preparation. It should be considered as a first line parenteral iron for all iron deficiency anaemia patients whether pregnant or not.

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